United States District Court
District of Massachusetts

United States ex rel. Richard Cohen,	)	
Plaintiff,	)	
v.	)	**Civil Action No. 23-11684-NMG**
Lahey Clinic Hospital, Inc.,	)	
Defendant.	)	

MEMORANDUM & ORDER

GORTON, J.

Richard Cohen ("Cohen" or "Relator"), a former patient of Lahey Clinic Hospital, Inc. ("Lahey" or "defendant"), brings this qui tam action on behalf of the United States of America under the False Claims Act, 31 U.S.C. §§3729(a)(1)(A)-(C) ("the FCA"). Cohen alleges that Lahey knowingly submitted reimbursement claims to Medicare for unused units of the drug botulinum toxin Type A (more commonly known as "BOTOX"), inducing the government to release funds to Lahey far in excess of Medicare billing guidelines.

Lahey moves to dismiss the action for failure to state a claim upon which relief can be granted. For the reasons that follow, the motion (Docket No. 27) will be allowed.

I. Background

A. Facts

Lahey is an incorporated Massachusetts hospital with a principal place of business in Burlington, Massachusetts. Relator is a resident of Dennis, Massachusetts, and a former patient of Lahey.

Relator suffers from irregular, involuntary muscle contractions, so-called "hemifacial spasms," on the left side of his face. To treat his ailment, Relator became a patient at Lahey's Burlington facility, where he was administered facial injections of BOTOX on a quarterly basis.

BOTOX is sold under two different brand names, "BOTOX therapeutic" and "BOTOX cosmetic," which are the same biological product. They are identical formulations and contain the same active ingredient. Government payors reimburse providers for the use of BOTOX therapeutic to treat multiple conditions including, as relevant here, hemifacial spasms. "The use of [BOTOX] for cosmetic purposes is statutorily non-covered" by Medicare. CMS, Medicare Coverage Database: Billing and Coding: Botulinum Toxins, last updated July 10, 2025, https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52848&ver=38&=.

BOTOX is administered to patients in "units." In the United States, BOTOX is sold in 50-unit, 100-unit and 200-unit

vials. Each vial contains vacuum-dried powder that a medical provider reconstitutes by injecting a saline solution into the vial and mixing it with the powder.[1] The reconstituted BOTOX is then drawn from the vial with an unused, sterile needle and syringe before being injected into the patient.

Once reconstituted, BOTOX must be administered within 24 hours. Any unused units within a reconstituted vial must be refrigerated during that 24-hour period. Due to its short shelf life, Medicare reimburses providers for unused portions of the drug post-reconstitution. Nevertheless, Centers for Medicare & Medicaid Services ("CMS") guidelines clarify that

> [t]he units billed must correspond with the smallest dose available for purchase from the manufacturers that could provide the appropriate dose for the patient.

CMS, MLN Matters Number: SE1316, Aug. 1, 2013 ("MLN SE1316").

Between July, 2020, and November, 2022, Cohen was administered nine injections of BOTOX and for each injection, he received between 16 and 20 units.

B. Procedural History

In January, 2025, Relator filed his single-count complaint in Massachusetts Superior Court for Plymouth County. He alleges that Lahey engaged in unfair and deceptive practices, in violation of M.G.L. c.93A ("Chapter 93A"). Attached to his

[1] A "reconstituted" solution is prepared by adding a solvent, typically water, to a dehydrated or concentrated form of a substance.

complaint, Mellen filed a Proof of Service ("POS") addressed to "IMDbPro/Amazon" at "535 Terry Avenue North, Seattle, WA 98019." Without waiving service of process, Lahey timely removed the case to this Court.

The government declined to intervene in April, 2024. Lahey filed its initial motion to dismiss and, shortly thereafter, Relator filed his amended complaint. In September, 2024, Lahey filed its motion to dismiss for failure to state a claim.

II. Motion to Dismiss

In its motion to dismiss, Lahey presents two arguments. First, it asserts that Relator has failed to state a claim under Fed.R.Civ.P. 12(b)(6). Specifically, it alleges that the Relator has proven neither falsity nor scienter. Second, Lahey argues that Relator has failed to plead a violation of the FCA with particularity as required under Fed.R.Civ.P. 9(b).

A. Standard of Review

To survive a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6), the subject pleading must state a claim for relief that is actionable as a matter of law and "plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible if, after accepting as true all non-conclusory factual allegations, the court can draw a reasonable inference that the defendant is liable for the alleged

misconduct Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011). The reviewing court may not disregard properly pled factual allegations even if actual proof of those facts is improbable. Ocasio-Hernandez, 640 F.3d at 12.

In bringing claims under subsection (a)(1) of the FCA, relators are held to the heightened pleading requirements of Fed.R.Civ.P. 9(b). U.S. ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009). Rule 9 requires pleading, at minimum, "the who, what, where, when, and how of the alleged fraud." United States ex rel. Worsfold v. Pfizer Inc., No. 09-11522, 2013 WL 6195790, at *5 (D. Mass. Nov. 22, 2013). Conclusory statements related to plans or schemes are insufficient. Id.

B. False Claims Act

Relator apparently brings claims under 31 U.S.C. §§3729(a)(1)(A) and (B). He claims that Lahey both

> knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval,

§3729(a)(1)(A), and

> knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim,

§3729(a)(1)(B). "Knowingly" is defined under the statute as requiring that a person

> (i)has actual knowledge of the information;

> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) acts in reckless disregard of the truth or falsity of the information.

§3729(b)(1)(A). Neither mistake nor negligence is sufficient to establish knowledge under the FCA. See United States v. President & Fellows of Harvard Coll., 323 F. Supp. 2d 151, 189 (D. Mass. 2004).

C. Application

Relator makes two distinct allegations of fraud. First, he asserts that Lahey used, and billed for, 100-unit vials of BOTOX when it should have used the available 50-unit vials. He contends that because Lahey was billing for the discarded units it was required to use the smallest (50-unit) vial available to provide the appropriate dose. Next, he argues that Lahey overbilled for the actual BOTOX used in conjunction with his treatment, totaling 1,034 falsely billed units. Both claims fail to meet the pleading requirements under Rule 12(b)(6) and Rule 9(b).

1. Relator has not established that billing for the 100-unit vials of BOTOX was false or fraudulent

Relator alleges that he should have been treated with the 50-unit vials of BOTOX, rather than the 100-unit vials, based on the requirements under MLN SE1316. He avers that he never required more than 20 units per treatment and therefore should

have been treated with the 50-unit vials rather than the 100-unit vials.

There are several problems with that argument. First, Lahey points out that MLN SE1316, which Relator relies on heavily for his assertion that Lahey should have billed the smallest dose available, was issued by CMS specifically with respect to the drugs Rituximab and Bevacizumab but not BOTOX. Relator represents that the guidance applies to general billing standards but Lahey's rebuttal is more compelling.

Even if the Court would interpret the pertinent language in MLN SE1316 as general billing standards, Relator has not alleged facts sufficient to show that the 50-vial units were "available" for his treatment. His allegation that such vials existed in the hospital is immaterial, as is his allegation that he was once treated with a 50-unit vial. He proffers no facts that would establish a regulatory or statutory basis sufficient to support the claim that the 50-unit vials were a valid, clinical option for his treatment. In essence, Relator has pled conclusory allegations that Lahey should have treated him with those vials but without ever establishing that it could have done so. See Pfizer Inc., No. 09-11522, 2013 WL 6195790 at *5 ("Conclusory accusations related to 'plans and schemes' are insufficient). Without such a showing, he has failed to state a claim upon which relief can be granted.

2. Relator has not pled facts sufficient to establish scienter

Relator has also failed to plead facts sufficient to establish that Lahey knowingly created false records material to a false or fraudulent claim. To be liable under the FCA, a defendant must have acted with knowledge, deliberate ignorance to the truth or reckless disregard to the truth.

Relator alleges that defendants knowingly created false records material to a false or fraudulent claim during nine of his visits. He contends that Lahey consistently billed for 180+ units of BOTOX for visits despite the fact that only one 100-unit vial was used. He also asserts that he spoke with a Lahey employee who acknowledged the bill was incorrect and that someone in the billing office would correct the error.

The allegations are insufficient to show that Lahey knowingly created a false record material to a false or fraudulent claim. At most, they demonstrate that a specific provider miscalculated the total units of BOTOX to be billed (units administered plus units discarded). Because miscalculations do not satisfy the scienter requirement found in the statute, Relator has failed to plead facts sufficient to state a claim under the FCA.

ORDER

For the forgoing reasons, defendant's Motion to Dismiss (Docket No. 26) is **ALLOWED**.

So ordered.

Nathaniel M. Gorton
Senior United States District Judge

Dated: September 30, 2025